UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

SENEA COYNE, *Plaintiff*,	§	CASE NO.: 1:21-cv-00086
v.	§	**COMPLAINT FOR DAMAGES AND JURY DEMAND**
COLOPLAST CORP., *Defendant*	§	

Plaintiff SENEA COYNE ("Plaintiff") files this Complaint and for causes of action against Defendant, COLOPLAST CORP. ("Defendant"), and alleges as follows:

INTRODUCTION

1. On or about November 5, 2008, Plaintiff SENEA COYNE was surgically implanted with an Aris™ Trans-Obturator Sling System ("Aris" or the "Product"), a pelvic mesh product and medical device designed, manufactured, and marketed by Defendant.

2. Although the system was intended to treat urinary incontinence, neither Plaintiff nor her healthcare providers were warned that the Aris was defective and negligently designed and manufactured. As a result of being surgically implanted with Defendant's unreasonably dangerous defective pelvic mesh device, Plaintiff has suffered, and continues to suffer, debilitating injuries, as described further herein. Plaintiff brings this suit for damages related to those injuries.

PARTIES

3. Plaintiff SENEA COYNE is, and was at all times relevant to this suit, a citizen and resident of San Marcos, Hays County, Texas.

4. Defendant Coloplast Corporation ("Coloplast" or "Defendant") is a corporation organized and existing under the laws of the State of Delaware, maintaining its principal place of business at 1601 West River Road North, Minneapolis, Minnesota 55411. Defendant may be served at its regular place of business or through its registered agent: CT Corporation System, 1999 Bryan St., Ste 900, Dallas, Texas 75201.

JURISDICTION AND VENUE

5. The Court has jurisdiction over this civil action pursuant to 28 U.S.C. § 1332(a) inasmuch as the amount in controversy exceeds $75,000 and the Plaintiff is a citizen of a different state than Defendant.

6. At all times material hereto, Defendant was engaged in the business of developing, manufacturing, designed, licensing, promoting, marketing, distributing, testing, warranting and/or selling in interstate commerce throughout the United States, including Texas, either directly or indirectly, medical devices intended to treat stress urinary incontinence and/or pelvic organ prolapse, including the Aris that was implanted into Plaintiff in Texas.

7. Venue in this district for pretrial proceedings in these civil actions is proper under 28 U.S.C. § 1391, inasmuch as a substantial part of the events or omissions giving rise to the claim occurred in this district. Specifically, Plaintiff, a resident of Hays County, Texas was surgically implanted with the Aris product in Hayes County at the San Marcos Surgery Center, 1891 Medical Parkway, San Marcos, Texas 78666.

8. Defendant is subject to *in personam* jurisdiction in the U.S. District Court, Western District of Texas, Austin Division, because Defendant placed defective products in the stream of commerce and all or some of those products were implanted into and caused personal injuries to Plaintiff, a resident of Hays County, Texas, in the State of Texas. Defendant has sufficient minimum contacts in Texas or otherwise intentionally avails itself of the Texas market through, without limitation, its advertisement, promotion, marketing, sales and/or distribution and other business activities, so as to render the exercise of jurisdiction over it by the Texas courts consistent with traditional notions of fair play and substantial justice.

FACTUAL BACKGROUND

Treatment of Pelvic Organ Prolapse and Stress Urinary Incontinence

9. At all times material to this action, Defendant was in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, advertising, and delivering, and introducing into interstate commerce, including, *inter alia*, within the United States and within the State of Texas, either directly or indirectly through third parties, subsidiaries or related entities, a line of pelvic mesh products (the "Pelvic Mesh Products"), including the Aris, the product implanted into Plaintiff. These products were designed primarily for the purpose of treating stress urinary incontinence as well as pelvic organ prolapse.

10. A pelvic organ prolapse ("POP") occurs when a pelvic organ, such as the bladder, drops ("prolapses") from its normal position and pushes against the walls of the vagina. Prolapse can happen if the muscles that hold the pelvic organs in place become weak or stretched from childbirth or surgery. More than one pelvic organ can prolapse at the same time. Organs that can be involved in a pelvic organ prolapse include the bladder, the uterus, the bowel and the

rectum.

11. Stress urinary incontinence ("SUI") is a type of incontinence characterized by leakage of urine during moments of physical stress, such as coughing, laughing, or sneezing. At all relevant times, the Aris was intended to be used, and for Plaintiff was used, to treat stress urinary incontinence.

12. Each of these Pelvic Mesh Products were cleared (not approved) for sale in the United States after the Defendant made assertions to the Food and Drug Administration of "Substantial Equivalence" under Section 510(k) of the Food, Drug and Cosmetic Act; this process does not require the applicant to prove safety or efficacy.

13. Surgical mesh is a medical device that is generally used to repair weakened or damaged tissue. This is the type of mesh used in Defendant's Pelvic Mesh Products, including the Aris product at issue in this case. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair POP or to support the urethra to treat SUI. Most pelvic mesh products, including the Aris product at issue in this case, are comprised of non-absorbable, synthetic, monofilament polypropylene mesh.

14. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in Plaintiff and others is biologically incompatible with human tissue, and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendant's Pelvic Mesh Products. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further

inflammation, chronic infectious response, and chronic pain. It also can cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the mesh.

15. When the Pelvic Mesh Products, including the Aris product at issue in this case, are inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

16. In 1996, the FDA cleared the first pelvic mesh products for use in the treatment of SUI. These products include products manufactured, marketed, and distributed by Defendant. These products were and are approved by the FDA under the abbreviated 510(k) approval process. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed before May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to these pelvic mesh products, including the Aris product at issue in this case.

History of the Aris Product

17. Many of the Defendant's Pelvic Mesh Products, including the Aris product at issue in this case, were developed and/or acquired as a result of the acquisition by Coloplast of Mentor Corporation ("Mentor")'s surgical, urological, clinical, and consumer healthcare business segments in June 2006.

18. On February 8, 2001, Mentor announced the purchase of Porges S.A., a subsidiary of Sanofi-Synthelabo. At the time, Porges held the leading market share for urological products in France and held a strong position throughout Europe was one of the largest manufacturers of urological products, supplying a complete range of products including pelvic

mesh products.

19. On January 24, 2005, Mentor applied for 510(k) clearance for a new product, the Aris(TM) Trans-Obturator Tape and Surgical Kit. In the 510(k) Summary (K050148) for the Aris, Defendant states "the Mentor Aris Trans-obturator Tape and the Kit are substantially equivalent in material, function, performance and design to the Mentor ObTape Trans-Obturator Tape and Surgical Kit cleared under 510(k) K031767 and K042851, respectively. It is also substantially equivalent to other urethral support tape products currently on the market." The Aris received 510(k) clearance from the FDA on March 9, 2005.

20. In May 2005, Mentor announced the U.S. launch of its new Aris(TM) Trans-Obturator Tape. According to Mentor's launch reports, "specifically designed to utilize Mentor's patented Trans-Obturator Technique (T.O.T.(TM)), Aris represents the newest technical achievement and advanced generation of trans-obturator slings for the treatment of stress urinary incontinence in women." "The introduction of Aris furthers Mentor's position as a pioneer of the trans-obturator method for treating stress incontinence in women," commented Joshua H. Levine, President and Chief Executive Officer of Mentor Corporation. "We are committed to driving innovation in the field of women's health to provide better solutions for physicians and the patients they serve." Analytic Biosurgical Solutions ("ABISS") FDA registration lists its proprietary device as "Mentor Aris Trans-Obturator Tape and Surgical Kit."

21. On October 12, 2005, ABISS and Mentor entered into a number of agreements pursuant to which ABISS licensed a number of ABISS' products to Mentor, which were thereafter marketed by Mentor under its trademarks, including its Aris trademark.

22. On June 2, 2006, Mentor sold its surgical, urological, clinical and consumer healthcare business segments to Coloplast for $461,145,398, including *inter alia*, Mentor's

October 12, 2005, agreements with ABISS and Mentor's Aris and Novasilk Pelvic Mesh Products.

23. At all times, the product marketed and sold in the United States as "Mentor Aris Trans-Obturator Tape and Surgical Kit" was manufactured by ABISS and, at all times after October 2, 2006, the product "Mentor Aris Trans-Obturator Tape and Surgical Kit" was exclusively marketed and sold in the United States by Coloplast Corp. from its principal place of business in Minneapolis, Minnesota.

24. ABISS is registered with the FDA, Registration Number 3004756681, as the manufacturer of "Mentor Aris Trans-Obturator Tape and Surgical Kit."

25. On December 5, 2005, Mentor obtained 510(k) clearance for Mentor NovaSilk Mesh. Mentor NovaSilk Mesh is a permanent, synthetic knitted propylene mesh that is square in shape and is a sterile, single use device. The Mentor NovaSilk Mesh obtained 510(k) clearance based on substantial equivalence in material, function, performance, and design to the Gynemesh Prolene Soft (Polypropylene) Mesh cleared under 510(k) K013718 and knitted polypropylene already in use under Mentor's Aris Sling cleared under 510(k) K050148. Joshua H. Levine, President and Chief Executive Officer of Mentor Corporation commented, "The addition of NovaSilk to Mentor's expanding portfolio of women's health products for pelvic organ prolapse or stress urinary incontinence reinforces the commitment of our urology franchise to surgeons and the patients they serve by providing high quality product offerings and customer service and support."

26. Coloplast Corp.'s annual report for 2009-2010 reported that "the majority of our acquired patents and trademarks are associated with the acquisition of Mentor's urology, business in 2006." The annual report also said that Mentor signed "a non-competition clause prohibiting

Mentor (the seller) from selling urology products for the next seven years…."

27. Coloplast Corp. began marketing the Exair Prolapse Repair System in May 2009 to treat pelvic organ prolapse. This product is made of NovaSilk Mesh, precut into the necessary shape with four mesh arms extending from the main body, which are used to implant the device. This product obtained 510(k) clearance based on its substantial equivalence with Coloplast Corp.'s (formerly Mentor's) NovaSilk Mesh, and Gynecare Prolift Total Pelvic Floor Repair System cleared under pre-market notification number K071512 on May 15, 2008.

28. On October 29, 2010, Coloplast Corp. acquired Mpathy Medical Devices, Inc. ("Mpathy"). Mpathy was founded in 2003, with the aim of developing less invasive surgical solutions for the treatment of female stress urinary incontinence and pelvic organ prolapse. Mpathy's core product lines included Minitape® and Omnisure® for stress urinary incontinence, and the Restorelle® family for pelvic organ prolapse. Defendant Coloplast Corp. said of the acquisition that Coloplast Corp.'s market position in Surgical Urology and Female Pelvic Health would immediately strengthen based on Mpathy's product portfolio including slings, mini-slings and meshes for stress urinary incontinence and pelvic floor repair and material portfolio including Smartmesh® technology.

29. Coloplast Corp.'s website describes its various products, including those for treating (i) "Pelvic Organ Prolapse" and (ii) "Stress Urinary Incontinence," including "Sling Procedures." A press release issued by Coloplast Corp. described Coloplast Corp.'s new corporate headquarters at 1601 West River Road in Minneapolis and stated that "Denmark-based Coloplast…selected north Minneapolis as the new home for its North American headquarters in 2006." According to the press release the new headquarters "will include one of the company's three global Innovation Centers."

Warnings Regarding Pelvic Mesh Products

30. On July 13, 2011, the FDA issued a new warning regarding serious complications associated with pelvic mesh products, such as the Pelvic Mesh Products manufactured, marketed, and distributed by Defendant. In this warning, the FDA indicated that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**." (emphasis in the original). The FDA had also received increased reports of complications associated with the pelvic mesh products used in both pelvic organ prolapse and stress urinary incontinence cases.

31. The FDA Safety Communication also stated, *"Mesh contraction* (shrinkage) is a *previously unidentified risk of* transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA . . . Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (emphasis in original).

32. The FDA Safety Communication further indicated that the benefits of using pelvic mesh products instead of other feasible alternatives did not outweigh the associated risks. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risks."

33. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the "White Paper"). In the White Paper, the FDA noted that published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

34. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risks." (Emphasis in original).

35. The White Paper further stated that "these products are associated with serious adverse events . . . Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair." In its White Paper, the FDA advises doctors to, *inter alia*, "[r]ecognize that in most cases POP can be treated successfully without mesh thus avoiding the risk of mesh related complications." The White Paper concludes by stating that the FDA "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

36. On August 25, 2011, Public Citizen, a consumer advocacy group, submitted a petition to the FDA seeking to ban the use of pelvic mesh products in pelvic repair procedures. In its Petition, Public Citizen warned that pelvic mesh products should be recalled because they offer no significant benefits but expose patients to serious risks and the potential for permanent life-altering harm. Joining Public Citizen as co-petitioners were Dr. L. Lewis Wall, a professor of obstetrics and gynecology at Washington University in St. Louis, and Dr. Daniel S. Elliott, a urologic surgeon specializing in female urology at the Mayo Clinic in Rochester, Minnesota.

37. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS") also identified physical and mechanical changes to the transvaginal mesh inside the body as a serious complication associated with transvaginal mesh, stating:

> **There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh… Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.**

38. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

39. As is known to Defendant, the risks associated with POP repair are the same as SUI repair. However, the data regarding the magnitude and frequency of these known risks are not as developed as the data on POP repair. The FDA recognized this, as demonstrated by its Section 522 Orders issued to manufacturers of pelvic mesh products used to treat SUI in January of 2012.

40. In September 2011, the FDA acknowledged the need for additional data and noted in "Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence" that the literature and information developing on SUI repair with Pelvic Mesh Products "indicates that serious complications can occur . . . [and] a case can be made for additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUI."

41. After the 2011 FDA notification that mesh complications from POP repairs were "not rare," a 2013 article was published that stated: "as outlined in the FDA notifications, patients should be forewarned that some transvaginal mesh complications are life altering and might not always be surgically correctable. Furthermore, that study noted that "the women who received both MUS and TM represented a complicated surgical group. Fifteen women (43%) required MUS takedown concurrently with prolapse mesh excision. Two-thirds of these women had associated chronic pelvic pain and vaginal pain, in addition to their urinary symptoms."

42. On April 16, 2019, the FDA ordered all manufacturers of surgical mesh intended for transvaginal repair of anterior compartment prolapse (cystocele) to stop selling and distributing its products immediately. In fact, the FDA has determined that the manufacturers, Boston Scientific and Coloplast specifically, have not demonstrated reasonable assurance of safety and effectiveness for these devices, which is the premarket standard that now applies to them since the agency reclassified them into class III (high risk) in 2016.[1]

43. Defendant did not, and has not, adequately studied the extent of the risks associated with its Pelvic Mesh Products. In January 2012, the FDA recognized the risk to women and mandated additional studies to further investigate these risks.

Defective Design

44. Defendant knew or should have known that its Pelvic Mesh Products, including the Aris product at issue in this case, unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks. At the time Defendant began marketing the Aris, Defendant was aware that the Aris was associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011, safety communication.

45. The Aris was designed to be permanently implanted into a woman's body yet the product changes after implantation; it contracts over time which *inter alia,* can pull or compress nerves, muscles, and other soft tissues important for sexual function, mobility, bowel function, and bladder function. These product changes occur while the product is implanted.

46. Moreover, despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in Plaintiff is biologically incompatible with human tissue

[1] www.fda.gov/medical-devices/implants-and-prosthetics/urogynecologic-surgical-mesh-implants.

and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendant's Pelvic Mesh Products, including the Aris product at issue herein. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, causes chronic inflammation of the pelvic tissue, causes shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain, cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the polypropylene mesh.

47. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction."

48. Defendant makes the following statements regarding its Pelvic Mesh Products:

[Aris has] Low rate of particle release from the sling-**minimizes increase in inflammatory response**. Atraumatic, smooth edges allow for easy passage during implantation. Macroporous design allows for optimal tissue integration. (emphasis added).

49. Contrary to Defendant's assertions that its products minimize increase in inflammatory response:

A. In September 2009, results from a study were published in the BMC Women's Health relating to the comparison of host response and complications in patients implanted with Coloplast's Aris. Implants from the Aris group showed an **increase risk of**

erosion which was quantified at 4%. Kaelin-Gambirasio I, *Complications associated with transobturator sling procedures: analysis of 233 consecutive cases with a 27 months follow-up*. BMC Womens Health. 2009 Sep 25; 9:28.

B. In September 2012, results from a study were published in the World Journal of Urology relating to the comparison of TVT vs TOT slings. 15 of 71 patients suffered adverse events including infection and erosion, **two thirds of which were implanted with the Aris.** Wadie BS, *TVT versus TOT, 2-year prospective randomized study*. World J Urol. 2012 Sep 26.

50. Defendant makes the following statements regarding its Pelvic Mesh Products:

> Novasilk is one of the lightest weight, thinnest meshes on the market, which translates into a more conforming mesh that may **reduce cases of inflammation, infection, or erosion** by having less implanted material.

51. Contrary to Defendant's assertions that its products are resistant to significant inflammation, infection or erosion:

A. Complications from mesh placement for pelvic organ prolapse include among other adverse events: acute and chronic infection, tissue contraction due to mesh shrinkage, erosion of the mesh into adjacent structures, and dyspareunia. [painful sexual intercourse]. Cosson, M., et al., *Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material?* Int Urogynecol J Pelvic Floor Dysfunct, 2003. 14(3): p. 169-78; discussion 178. Jones, K.A., et al., *Tensile properties of commonly used prolapse meshes.* Int Urogynecol J Pelvic Floor Dysfunct, 2009. 20(7): p. 847-53. Margulies, R.U., et al., *Complications requiring reoperation following vaginal mesh kit procedures for prolapse.* Am J Obstet Gynecol, 2008. 199(6): p. 678 e1-4.

B. Erosion can be defined as the mesh wearing, or slowly grinding through the vaginal wall. This is a serious complication and moreover, there is evidence that meshes shrink *in vivo* leading to increased stiffness, pain and poor restoration of the normal properties of the vagina. Dora, C.D., et al., *Time dependent variations in biomechanical properties of cadaveric fascia, porcine dermis, porcine small intestine submucosa, polypropylene mesh and autologous fascia in the rabbit model: implications for sling surgery.* J Urol, 2004. 171(5): p. 1970-3.

C. Larger pores within polypropylene mesh materials, allowing macrophage and leukocyte migration, reduce infection. Birch C, Fynes MM. The role of synthetic and biological prosthesis in reconstructive pelvic floor surgery. *Curr Opin Obstet Gynecol*. 2002; 14:527–595. 22. Govier FE, Kobashi KC, Kozlowski PM, Kuznetsov DD, Begley SJ, McGonigle KF, et al. High complication rate identified in sacrocolpopexy patients attributed to silicone mesh. *J Urol*. 2005; 65:1099–1103.

D. In a study published in August 2012, Defendant's Novasilk was compared to other polypropylene on the market relating structural properties. Novasilk was found to have less porosity and increased stiffness than several of the other studied products—supporting clinical observations among Plaintiff's surgeons and the causative conclusion that properties of Defendant's mesh led to Plaintiff's complications. Feola A, *Characterizing the ex vivo textile and structural properties of syntheticprolapse mesh products*. Int Urogynecol J. 2012 Aug 11.

52. Defendant's Pelvic Mesh Products, including the Aris product at issue, were and are unreasonably susceptible to degradation and fragmentation inside the body, shrinkage or contraction inside the body, intense foreign body reaction, chronic inflammatory response, chronic

wound healing, chronic infections in and around the mesh fibers, and nerve entrapment in the collagen scar formation. Defendant knew or should have known of these serious risks and should have, therefore, warned physicians and patients regarding these risks to the extent they were known or knowable.

53. To this day, the Aris continues to be marketed to the medical community and to patients as a safe, effective, and reliable medical device, implanted by safe, effective, and minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of POP and SUI, and other competing products.

54. Defendant omitted and downplayed the risks, dangers, defects, and disadvantages of its Pelvic Mesh Products, including the Aris product at issue, and advertised, promoted, marketed, sold and distributed the its Pelvic Mesh Products, including the Aris product at issue, as safe medical devices when Defendant knew or should have known that the Pelvic Mesh Products were not safe for their intended purposes, and that the products would cause, and did cause, serious medical problems, and in many patients, including Plaintiff, catastrophic injuries. Further, while some of the problems associated with the pelvic mesh products, including the Aris, were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

55. Contrary to Defendant's representations and marketing to the medical community and to the patients themselves, its Pelvic Mesh Products, including the Aris product at issue, have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff, making them defective under the law.

56. Defendant failed to design and establish a safe, effective procedure for removal of its Pelvic Mesh Products, including the Aris product at issue, or to determine if a safe, effective procedure for removal of the Pelvic Mesh Products exists.

57. Feasible, suitable, and safer alternative designs to Defendant's Pelvic Mesh Products, including the Aris product at issue, have existed at all times relevant and in reasonable probability would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility. Said safer alternative designs were economically and technologically feasible at the time the Aris product left the control of Defendant by the application of existing or reasonably achievable scientific knowledge. Said safer alternatives designs include, but are not limited to: (1) traditional abdominal surgery using sutures to attach the urethra to a ligament in the pelvis (known as the "Burch procedure"); (2) autologous fascia sling; (3) an allograft sling such as Repliform; (4) a retropubic sling; and (5) a retropubic sling with less polypropylene, such as Ultrapro.

58. The specific nature of defects for Defendant's Aris device at issue in this case includes, but is not limited to, the following:

A. The use of polypropylene in the Aris and the adverse tissue reactions and host defense response that result from such material, causing adverse reactions and serious, permanent injuries including, but not limited to, painful recurrent erosions and associated intractable pain;

B. The design of the Aris to be inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden leading to excessive blood loss and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted mesh causing chronic

infections, subclinical infections and biofilms, enhanced chronic inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries;

C. The use and design of arms and hooked anchors in the Aris sling, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

D. The procedure to place the Aris sling requires blindly placing the arms the device through the thigh and obturator fossa that can injure major nerves that contribute to sexual function, contribute to mobility, and contribute to bowel and bladder function;

E. Biomechanical issues with the design of the Aris which results in a non-anatomic condition leading to contraction or shrinkage of the mesh inside the body, that in turn causes surrounding tissue to become eroded, inflamed, fibrotic and infected, resulting in serious and permanent injury;

F. The propensity of the mesh design characteristics of the Aris for plastic deformation when subjected to tension both during implantation and once implanted inside the body which causes the mesh, or portions thereof, to be encapsulated in a rigid scar plate which leads to nerve entrapment, bacterial entrapment, tissue destruction, enhanced inflammatory and fibrotic response and chronic pain;

G. The propensity of the mesh used in the Aris to become rigid and inflexible, causing it to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where the product is implanted, and causing discomfort and pain with normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

H. The propensity of the mesh used in the Aris for degradation or fragmentation over time, which causes an increased surface area that leads to enhanced chronic inflammatory and fibrotic reaction, causes a "barbed wire" or "saw blade" effect by the fragmented surface "sawing" through the tissue, leads to bacteria harboring in the fragmented, peeled and split fiber surface which in turn leads to chronic infections at the mesh surface, and results in continuing injury over time; and

I. The inability of surgeons to effectively treat many of these conditions due to the integration of the mesh into the pelvic tissue and thus the inability to safely remove or excise the mesh once a complication occurs.

Failure to Warn/Inadequate Warnings & Instructions

59. The Aris is also defective due to Defendant's failure to adequately warn or instruct Plaintiff and/or her health care providers after the product left the manufacturer and before and after implantation of the Aris of subjects including, but not limited to, the following:

A. The Product's propensities to contract, retract, and/or shrink inside the body;

B. The Product's propensities for degradation, fragmentation and/or migration;

C. The Product's inelasticity preventing proper mating with the pelvic floor and vaginal region;

D. The frequency and manner of transvaginal mesh erosion or extrusion resulting from the Product;

E. The risk of chronic inflammation resulting from the Product;

F. The risk of chronic infections resulting from the Product;

G. The risk of permanent vaginal or pelvic scarring resulting from the Product;

H. The risk of *de novo* urinary dysfunction resulting from the Product;

I. The risk of *de novo* dyspareunia or painful sexual intercourse resulting from the Product;

J. The risk of recurrent, intractable pelvic pain and other pain resulting from the Product;

K. The need for corrective or revision surgery to adjust or remove the Product which in some cases is not feasible nor possible;

L. The severity of complications that could arise as a result of implantation of the Product;

M. The hazards associated with the Product;

N. The Product's defects described herein;

O. Treatment of stress urinary incontinence with Defendant's Product is no more effective than feasible, available and safer alternatives;

P. Treatment of stress urinary incontinence with Defendant's Product exposes patients to greater risk than feasible, available and safer alternatives;

Q. Treatment of stress urinary incontinence with the Product makes future surgical repair more difficult than feasible, available and safer alternatives;

R. Use of the Product puts the patient at greater risk of requiring additional surgery than feasible, available and safer alternatives;

S. Removal of the Product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;

T. Complete removal of the Product may not be possible and may not result in complete resolution of the complications, including pain; and

U. The nature, magnitude, and frequency of the complications that could arise as a result of implantation of the Product.

60. Defendant underreported and continues to underreport information about the

propensity of its Pelvic Mesh Products, including the Aris product at issue, to fail and cause injury and complications and have made unfounded representations regarding the efficacy and safety of the Pelvic Mesh Products through various means and media.

61. Defendant underreported and continues to underreport information about the propensity of its Pelvic Mesh Products, including the Aris product at issue, to fail and to cause injury and complications and have made unfounded representations regarding the efficacy and safety of its Pelvic Mesh Products, including the Aris product at issue, through various means and media.

62. Defendant failed to perform proper and adequate testing and research in order to determine and evaluate the nature, magnitude and frequency of the risks attendant to its Pelvic Mesh Products, including the Aris product at issue.

63. The Aris product at issue was at all times utilized and implanted in a manner intended and/or foreseeable to Defendant, as Defendant generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physician.

64. Defendant knowingly provided incomplete and insufficient training and information to physicians regarding the use of its Pelvic Mesh Products, including the Aris product at issue, and the aftercare of patients implanted with those Pelvic Mesh Products.

65. At all relevant times herein, Defendant continued to promote its products as safe and effective even when no clinical trials had been done supporting long-term or short-term efficacy or safety.

66. In doing so, Defendant failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with its Pelvic Mesh Products, including the magnitude and frequency of these risks.

67. At all relevant times herein, Defendant failed to provide sufficient warnings and instructions that would have put Plaintiff, the medical community, Plaintiff's treating physicians, and the general public on notice of the dangers and adverse effects caused by implantation of the Defendant's Pelvic Mesh Products, including the Aris product at issue.

68. Defendant's Pelvic Mesh Products, including the Aris product at issue, as designed, manufactured, distributed, sold and/or supplied by Defendant, were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendant's knowledge of lack of safety.

69. The risk of serious injuries was known or should have been known to Defendant, but in spite of these risks, Defendant continued to market the Aris for transvaginal use to physicians and patients, including Plaintiff and Plaintiff's healthcare providers, without adequate warnings.

Resulting Injury from Defendant's Pelvic Mesh Products

70. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with Defendant's Pelvic Mesh Products include, but are not limited to: erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain, emotional distress and mental anguish, and other debilitating complications. In addition, affected women, including Plaintiff, will need to be continuously monitored because of being implanted with Defendant's Pelvic Mesh Products.

71. In many of these cases, including that of the Plaintiff, women have had or will have to undergo extensive medical treatment, including, but not limited to, operations to locate

and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia. Removal of contracted, eroded and/or infected transvaginal mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

72. The medical and scientific literature studying the effects of pelvic mesh products, like that of the Aris product implanted in Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the pelvic mesh products.

Facts Specific as to Plaintiff

73. On November 5, 2008, at San Marcus Surgery Center, 1891 Medical Parkway, San Marcos, Texas 78666, Lance Ledoux, M.D., implanted Plaintiff SENEA COYNE with a Coloplast Aris Trans-Obturator Sling, Ref. # 93-4400, Lot #1670891, a medical device designed, manufactured, and marketed by Defendant for treatment of stress urinary incontinence.

74. The Aris implanted in Plaintiff was in the same or substantially similar condition as it was when it left Defendant's possession, and in the condition directed by and expected by Defendant. Plaintiff's treating physicians implanted the Aris properly and appropriately.

75. Although the system was intended to treat SUI, neither Plaintiff nor her healthcare providers were warned that the Aris was defective and negligently designed and marketed, as discussed further herein.

76. After ongoing bleeding, urinary issues, and problems with intercourse led her to seek medical treatment, Plaintiff was told for the first time on March 13, 2019, by Koteswara Kunda, M.D. of San Marcos Women's Health that she had an exposed portion of mesh from the Aris product in her vagina. This was confirmed by a visit to Gassau S. Freiha, M.D. of Tri-County

Urology on April 8, 2019, who instructed Plaintiff that she needed to have the mesh removed.

77. On November 6, 2019, Plaintiff underwent a partial mesh explantation procedure with placement of an autologous pubofascial sling performed by Dr. Stephen Kraus of UT-Health San Antonio.

78. Today, Plaintiff continues to experience problems, groin pain, pelvic pain, vaginal pain, painful intercourse, and urinary problems and requires ongoing medical care for her painful mesh-related conditions.

DISCOVERY RULE

79. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and to the extent necessary would allege as follows:

80. Plaintiff could not have reasonably discovered the occasion, manner and/or means by which Defendant's breach of duty occurred until within two years of the filing of this complaint. Further, Plaintiff did not and, exercising reasonable diligence, including consultation with medical professionals, could not discover the existence of her legal cause of action or the injuries caused by Defendant's breach of duty and/or defective products until within two years of the filing of this complaint. Defendant continues to deny that its products are defective or cause injuries such as those suffered by Plaintiff and Defendant continues to manufacture, market, and sell all or some of the products at issue. Any applicable statute of limitations has been tolled by the knowing and active concealment and denial of material facts known by Defendant when Defendant had a duty to disclose and/or by the application of the discovery rule.

FIRST CAUSE OF ACTION
[Negligence]

81. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein.

82. At all times herein mentioned, Defendant was engaged in the business of researching, manufacturing, licensing, fabricating, designing, labeling, distributing, using, supplying, selling, marketing, warranting, packaging and advertising the Aris pelvic mesh product at issue in this case.

83. Defendant owed to Plaintiff and the public a duty to act reasonably and to exercise ordinary care in pursuit of the activities mentioned above, and Defendant breached said duty of care.

84. At all times relevant hereto, Defendant owed to Plaintiff and the public a duty to act reasonably and to exercise ordinary care with respect to the safe, legal, and proper manufacture, license, design, formulation, distribution, production, processing, assembly, testing, inspection, research, marketing, labeling, packaging, preparation for use, issuance of warnings with respect to use, promotion, advertising, sale, and safety monitoring of the Aris, and to adequately test and warn of the risk and dangers of the Aris, both before and after sale.

85. Additionally, Defendant owed to Plaintiff and the public a duty to provide accurate, reliable, and completely truthful information regarding the safety and any dangerous propensities of the Aris manufactured, used, distributed, and/or supplied by them and to provide accurate, reliable, and completely truthful information regarding the failure of the Aris to perform as intended or as an ordinary consumer would expect.

86. At all times relevant hereto, Defendant breached the aforementioned duties in that Defendant negligently and carelessly manufactured, fabricated, designed, licensed, produced, compounded, assembled, inspected or failed to inspect, tested or failed to test, inadequately warned or failed to warn of the health hazards, labeled, distributed, handled, used, supplied, sold, marketed, warranted, packaged, promoted, and advertised the Aris in that said Aris caused,

directly and proximately, the injuries of Plaintiff through failure of the Aris to perform as intended or as an ordinary consumer would expect. Specifically, Defendant violated the duties of ordinary care and skill owed by Defendant to Plaintiff in the following particular respects:

a. Failing to conduct adequate and appropriate testing of its Pelvic Mesh Products such as the Aris to ensure they were safe for implantation in the female pelvis;

b. Putting its Pelvic Mesh Products such as the Aris on the market without first conducting adequate testing to determine possible side effects;

c. Putting its Pelvic Mesh Products such as the Aris on the market without adequate testing of its dangers to humans;

d. Failing to recognize the significance of the medical literature, its own testing, and/or the testing of, and information regarding its Pelvic Mesh Products such as the Aris, when said literature/testing evidenced such products' potential harm to humans;

e. Failing to respond appropriately and promptly to the medical literature, its own testing, and/or the testing of, and information regarding its Pelvic Mesh Products such as the Aris, when said literature/testing evidenced such products' potential harm to humans;

f. Failing to promptly and adequately warn of the potential of its Pelvic Mesh Products such as the Aris to be harmful to humans;

g. Failing to promptly, adequately, and appropriately recommend testing and monitoring of the patients of its Pelvic Mesh Products, including patients implanted with the Aris product, in light of the knowledge that said Pelvic Mesh Products had the potential to be harmful to humans;

h. Failing to properly, appropriately, and adequately monitor the post-market performance of Defendant's Pelvic Mesh Products, including the Aris, as well as said products' effects on patients;

i. Concealing from the FDA, the National Institutes of Health, the general medical community and/or physicians, its full knowledge and experience regarding the potential that Defendant's Pelvic Mesh Products, including the Aris, could be harmful to humans;

j. Promoting, marketing, advertising and/or selling Defendant's Pelvic Mesh Products, including the Aris, for use on patients given their knowledge and experience of said Pelvic Mesh Products' potential harmful effects;

k. Failing to withdraw its Pelvic Mesh Products, including the Aris, from the market, restrict their use and/or adequately warn of said Pelvic Mesh Products' potential dangers, given its knowledge of the potential for harm to humans;

l. Failing to fulfill the standard of care required of a reasonable, prudent, urogynecological medical device manufacturer engaged in the design, manufacturer, and marketing of its Pelvic Mesh Products, including the Aris;

m. Placing and/or permitting the placement of Defendant's Pelvic Mesh Products, including the Aris, into stream of commerce without warnings of the potential for said Pelvic Mesh Products to be harmful to humans and/or without properly warning of said Pelvic Mesh Products' dangerousness;

n. Failing to disclose to the medical community in a timely and appropriate manner, facts relative to the potential of Defendant's Pelvic Mesh Products, including the Aris, to be harmful to humans;

o. Failing to respond or react promptly and appropriately to reports of Defendant's Pelvic Mesh Products, including the Aris, causing harm to patients;

p. Disregarding the safety of users and consumers of the Aris and Defendant's other Pelvic Mesh Products, including Plaintiff, under the circumstances by failing to adequately warn of said Pelvic Mesh Products' potential harm to humans;

q. Disregarding the safety of users and consumers of the Aris and Defendant's other Pelvic Mesh Products, including Plaintiff, and/or her physicians and/or hospital, under the circumstances by failing to withdraw said Pelvic Mesh Products from the market and/or restricting their usage;

r. Disregarding publicity, government and/or industry studies, information, documentation, and recommendations, consumer complaints and reports and/or other information regarding the hazards of Defendant's Pelvic Mesh Products and their potential harm to humans;

s. Failing to exercise reasonable care in informing physicians and/or hospitals using Defendant's Pelvic Mesh Products, including the Aris, about its knowledge regarding said Pelvic Mesh Products' potential harm to humans;

t. Failing to remove its Pelvic Mesh Products, including the Aris, from the stream of commerce;

u. Failing to test its Pelvic Mesh Products, including the Aris, properly and/or adequately so as to determine their safety for use;

v. Promoting its Pelvic Mesh Products, including the Aris, as safe and/or safer than other comparative methods/products;

w. Promoting its Pelvic Mesh Products, including the Aris, on websites aimed at creating user and consumer demand;

x. Failing to conduct and/or respond to post-marketing surveillance of complications and injuries resulting from its Pelvic Mesh Products, including the Aris;

y. Failing to use due care under the circumstances; and

z. Failing to monitor, analyze, and report to the FDA, medical community, its product users, and/or physicians and/or hospitals, adverse post-surgical outcomes stemming from the use of its Pelvic Mesh Products, including the Aris.

88. The acts of Defendant constitute violations of the duty of ordinary care and skill owed by Defendant to Plaintiff.

89. Plaintiff used and was implanted with Defendant's Aris in a manner that was reasonably foreseeable.

90. As the direct and proximate result of Defendant's negligent and/or reckless and/or wanton breaches of its aforementioned duties with respect to the Aris, Plaintiff suffered the injuries and damages alleged herein.

91. WHEREFORE, said Plaintiff prays for judgment against Defendant.

SECOND CAUSE OF ACTION
[Strict Liability: Design]

92. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein.

93. Additionally, or in the alternative, if same be necessary, Plaintiff re- alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

94. Defendant was and is engaged in the business of selling its pelvic mesh products, including the Aris, in the State of Texas.

95. Defendant is a manufacturer and/or supplier of Pelvic Mesh Products, specifically the Aris, and is strictly liable to Plaintiff for designing, creating, manufacturing, distributing, selling and placing its Pelvic Mesh Products, specifically the Aris, into the stream of commerce.

96. The Aris product manufactured, designed, marketed, promoted, and sold by Defendant was expected to, and did, reach Plaintiff without substantial change in the condition in which it was sold and in the condition directed by and expected by Defendant. The Aris was defective at the time of manufacture, development, design, production, testing, inspection, endorsement, prescription, sale and distribution, and at the time it left the possession of the Defendant.

97. Defendant's Pelvic Mesh Products, specifically the Aris, manufactured and/or supplied by Defendant, were defective in design or formulation in that, when they left the hands of Defendant, they were unreasonably dangerous, taking into consideration the utility of these products and the risks involved in their use.

98. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendant, Plaintiff has suffered and continues to suffer devastating injuries and damages, and continues to require medical treatment due to these injuries.

99. Thus, Defendant is strictly liable to Plaintiff and said Plaintiff prays for judgment against Defendant.

THIRD CAUSE OF ACTION

[Strict Liability: Marketing/Failure to Warn]

100. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein.

101. Defendant supplied the Aris product that was implanted in Plaintiff.

102. At all times mentioned herein, Defendant's Pelvic Mesh Products, including the Aris product at issue, were dangerous and presented a substantial danger to patients who were implanted with them.

103. The risks and dangers associated with the Pelvic Mesh Products were known to Defendant at the time of implantation in Plaintiff, yet Defendant failed to provide warnings of such risks and dangers to Plaintiff.

104. Ordinary consumers would not have recognized the potential risks and dangers the Pelvic Mesh Products posed because their uses were specifically promoted to improve the health of such patients while the nature and prevalence of such risks were either downplayed or not provided to consumers and their physicians.

105. Defendant's Pelvic Mesh Products were used by Plaintiff in a way reasonably foreseeable to Defendant, particularly given the educational material or instructions given to physicians in regard to these products.

106. The failure of the Defendant to adequately warn about the risks and dangers associated with the Pelvic Mesh Products, including the Aris product at issue, was a proximate cause of the damages and injuries to Plaintiff.

107. Thus, Defendant is strictly liable to Plaintiff and said Plaintiff prays for judgment against Defendant.

DAMAGES

108. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

General and Special Damages

109. As a direct and proximate result of having the Aris implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury which includes or more likely than not may include, *inter alia,* any of the following: pudendal neuralgia, obturator neuralgia, pelvic floor tension myalgia, hip adductor myalgia, complex regional pain syndrome, erosion, recurrent urinary tract infections, interstitial cystitis, chronic dyspareunia, bowel and bladder dysfunction, and anorectal pain will likely undergo medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

110. Plaintiff's injuries, as will be more fully established in discovery, are of the exact type reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

111. The injuries suffered by Plaintiff were caused by the wrongful acts and omissions of Defendant.

Exemplary Damages

112. At all times relevant herein, Defendant:

a. Knew that its Pelvic Mesh Products, including the Aris, were dangerous, ineffective, and caused significant, life-altering complications and side-effects;

b. Concealed the dangers and health risks from Plaintiff, physicians, hospitals, other medical providers, the FDA, its users and the public at large;

c. Made misrepresentations to Plaintiff, physicians, hospitals, other medical providers, its users and the public at large as to the safety and efficacy of its Pelvic Mesh Products, including the Aris; and

d. With full knowledge of the health risks associated with its Pelvic Mesh Products, including the Aris, and without adequate warnings of the same, manufactured, designed, marketed, promoted, developed, sold and/or distributed its Pelvic Mesh Products, including the Aris, for routine use.

113. Defendant, by and through its officers, directors, managing agents, authorized sales representatives, employees and/or other agents engaged in acts and/or omissions involving subjective awareness of an extreme degree of risk, indicating conscious indifference to the rights, safety, or welfare of others. As such, the conduct of Defendant warrants the imposition of exemplary damages under all applicable legal standards.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands trial by jury, and pray for judgment against Defendant as follows:

1. A judgment against Defendant holding it liable for compensatory damages in a reasonable amount determined to be fair and just by the jury in this cause sufficient to adequately compensate Plaintiff for her harms and losses, including but not limited to damages:

a. For past and future general damages, the exact amount of which has yet to be ascertained, in an amount which will conform to proof at time of trial;

b. For past and future economic and special damages, according to proof at the time of trial;

c. For past and future medical and incidental expenses, according to proof at the time of trial;

d. For past and future loss of earnings and impaired earning capacity, according to proof at the time of trial;

e. For past and future physical disfigurement; and

f. For past and future pain and suffering, as well as mental and emotional distress, according to proof at the time of trial.

2. For punitive and exemplary damages in a reasonable amount determined to be fair and just by the jury;

3. For costs, attorneys' fees, interest, or any other relief, monetary or equitable, to which she is entitled; and

4. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues in the above captioned matter.

Dated this 28th day of January, 2021.

Respectfully submitted,

/s/ Ben C. Martin

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